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IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

**BRIEF OF AMICI CURIAE
UNIVERSITY OF MINNESOTA AND
TULANE UNIVERSITY IN SUPPORT OF
RESPONDENT MEDTRONIC, INC.**

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INTEREST OF THE AMICI CURIAE

The University of Minnesota and Tulane University (the "Academic Research Centers") jointly submit this brief amici curiae in support of Respondent Medtronic, Inc. on the writ of *certiorari* to the United States Court of Appeals for the Federal Circuit.

The Academic Research Centers are institutions of higher learning that are concerned about preserving a broad experimental use exemption to patent infringement to foster research and the expansion of knowledge, and who support in particular the exemption from infringement extended to FDA testing of medical products by section 271(e)(1) as construed by the Federal Circuit. The Academic Research Centers are engaged in extensive research in the medical field (as well as in other fields), and the decision of this Court could define the boundaries of the freedom to conduct that research. We are participating in this matter to urge the Court to consider the interest of U.S. Academic Research Centers in conducting all forms of research without being subject to limitations that interfere with the advancement of science and knowledge in this country.¹

The Academic Research Centers conduct research that is both publicly and privately sponsored. In many instances, private sponsors fund research on products that they intend to market. Income from sponsors of that research, and later from licenses with commercial entities, represents a significant and increasing source of funding for teaching and research institutions in the United States. If the Federal Circuit decision is reversed, that source of funding for improvements in medical device technology could be threatened.

It has been suggested by petitioner and its supporters that research can be conducted outside of the United States. It is, however, both unfair and shortsighted to suggest that this could be done without causing a shift

1. Tulane University has no clinical, financial, or service affiliation with Medtronic. Medtronic does, however, maintain a cardiovascular research program at the University of Minnesota Medical School, and has endowed a chair at the recently established biomedical engineering center. The medical school is an approved clinical investigation center for the Medtronic Model 7216A PCD device and separately contracts from time to time to conduct clinical research on other medical devices.

of both expertise and funding to foreign markets. Corporate sponsorship would dry up. The U.S. medical products field, in particular, would suffer as the result of work and innovation performed beyond its borders.

The Academic Research Centers have a common interest shared by other similarly oriented institutions in preserving the freedom to do research, fostering advances in science and technology, and educating America's future scientists, engineers, and physicians. Those interests are congruent with the public interest of promoting the progress of science and the useful arts. This Court is requested both to affirm the Federal Circuit decision on *certiorari* to allow for FDA testing of medical devices prior to patent expiration and to reassert the traditional experimental use exception consistent with the policies behind the Constitution.

SUMMARY OF THE ARGUMENT

Pursuant to the power given by Article I, Section 8, clause 8 of the U.S. Constitution "To Promote the Progress . . . Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries," Congress has provided that a patentee may exclude others from making, using, or selling the patented invention in the United States during the term of the patent. 35 U.S.C. § 154. However, Congress has given no definitions of these prohibited activities, leaving that task to the courts.

Further, while promotion of scientific and technical progress is accomplished by inducing inventors to disclose, and ultimately to dedicate to the public, beneficial advances in knowledge and technology by awarding them a limited period in which they can profit from their invention to the exclusion of others, the reward of the individual is secondary to the public benefit. It would not be in the public interest to prevent basic research in the field of a patent for up to twenty-two years as is being